

REMARKS

Introductory Comments

Reconsideration of the above-identified application in view of the arguments set forth herein is respectfully requested.

Claims 1-2, 4-17 and 26 are pending and under consideration.

Interview Summary

The undersigned attorney thanks the Examiner for her time during the telephone interview conducted on January 27, 2006. During this telephone interview, the rejection of claims 1-17 and 26 under 35 U.S.C. Section 112, first paragraph was discussed.

Rejection of Claims 1-17 and 26 Under 35 U.S.C. § 112, First Paragraph

Claims 1, 2, 4-17 and 26 are rejected under 35 U.S.C. § 112, first paragraph, as failing to comply with the written description requirement. The Examiner alleges that the claims contain subject matter, which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventors, at the time the application was filed, had possession of the claimed invention. Applicants respectfully traverse the rejection.

Specifically, the Examiner states that the specification fails to disclose the term "unconjugated" as recited in the claims. Thus, the Examiner maintains the rejection made in the previous Office Action.

As discussed in Applicants previous Amendments, while the specification may not provide *in haec verba* support for the term "unconjugated", Applicants submit that this term is inherent based on the description contained in the

specification. In support thereof, Applicants herein submit a Declaration of Richard L. Scopp pursuant to 37 C.F.R. Section 1.132 (hereinafter "Declaration"). Dr. Scopp is one of the inventors of the above-identified application.

The claimed invention relates to methods of decreasing interferences in specific binding assays. Specifically, the invention is based on the discovery that the addition of an effective amount of a large, unconjugated polycation in a serum or plasma assay is capable of decreasing interferences in said assays which typically result in inaccurate readings. More specifically, the polycation is simply included in the specific binding assay as an additive, such as part of the diluent. When the polycation is added to the assay as recited in the claims, it is not/has not been conjugated to any other molecule (See Paragraph 4 of the Declaration).

Applicants submit that it would be readily apparent to one skilled in the art, that the term "unconjugated" is inherently disclosed in the specification, particularly at pages 2-4, 6 and Examples 2-4 of the specification (See Declaration, Paragraph 5).

As mentioned previously herein, the polycation used in the methods of the claimed invention is unconjugated. The specification on page 6, lines 11-22 describes in detail suitable amounts and types of polycations that can be used in the claimed methods. No mention of conjugation to other molecules is described.

In Example 2, lines 14-17, the specification states "[I]n separate experiments, a polycation, i.e., polylysine, polybrene or MERQUAT, then was added to the TSH Assay Diluent and combined with the serum or plasma sample (150 μ L) and anti- β TSH antibody coated paramagnetic microparticles (50 μ L at 0.1% solids) in the first step of the TSH assay" (emphasis added).

In Example 3, lines 26-28 the specification states, "[I]n these experiments, a polycation, in particular, a poly-amino acid, was substituted in place of dextran sulfate in the microparticle diluent. The assay then was performed as described in the general procedure above."

The Office Action argues that with respect to the TSH assay described in Example 2 that the polycation could be conjugated to other molecules such as BSA for blocking non-specific binding on a solid phase. This is merely speculation that does not support the rejection. As discussed previously herein and in the Declaration, in the present invention, the polycation is not conjugated to any molecules (including BSA) when it is added to the assay samples. In fact, had BSA been conjugated to a polycation when it was added to the assay samples as argued by the Examiner, a description of the conjugation reaction, and the resulting conjugate would have been provided. (See Declaration, Paragraph 6). The purpose of such a conjugate would have also been described. *Id.*

There is nothing in Examples 2 and 3 to suggest that the polycations added to assay samples are conjugated. As discussed in the Declaration, certainly if these polycations were conjugated to one or more other molecules, these molecules would be identified as being included in the immunoassay and the method of their preparation would be explicitly described. *Id.* Their function in the immunoassay would also be identified. *Id.* As further discussed in the Declaration, when describing a molecule designed to reduce interference in a method of reducing interferences, one skilled in the art, such as Dr. Scopp, would not fail to describe any other molecules that are conjugated to the interference-reducing molecule, nor would one skilled in the art expect others in the field to neglect to include such a description. *Id.* Therefore, according to Dr. Scopp, those skilled in the art would immediately and clearly understand that the polycations described in the above-identified application do not contain any other molecules conjugated to them. *Id.*

Applicants submit that it would be clear to one skilled in the art that after reading Applicants specification that Applicants claimed method inherently discloses the addition of unconjugated polycations to specific binding assays for the purpose of decreasing interferences. As discussed in the Manual of Patent Examining Procedure in Section 2163.07(a) (8th Edition, Rev. 2, May 2004), when a patent application discloses that a device inherently performs a function or has a certain property or operates according to a theory or has an advantage, a patent application necessarily discloses that function, theory or advantage, even though it says nothing explicit concerning it (emphasis added). Therefore, based on the portions of the specification discussed above, Applicants have inherently disclosed that the polycations used in the claimed methods are unconjugated. Therefore, Applicants submit that the specification reasonably conveys to those skilled in the art that at the time this application was filed that Applicants were in possession of the claimed invention.

Thereupon, for the above reasons, Applicants respectfully request withdrawal of the rejection of claims 1, 2, 4-17 and 26 under 35 U.S.C. § 112, first paragraph, as failing to comply with the written description requirement.

Applicants also thank the Examiner for acknowledging that claims 1, 2, 4-17 and 26 are allowed over the prior art.

CONCLUSION

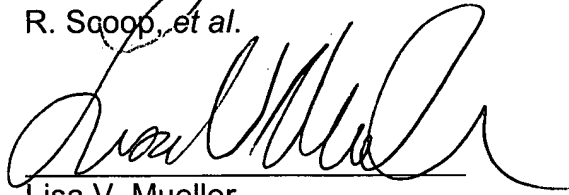
Applicants respectfully submit that the claims comply with the requirements of 35 U.S.C. Section 112. Accordingly, a Notice of Allowance is believed in order and is respectfully requested.

Should the Examiner have any questions concerning the above, she is respectfully requested to contact the undersigned at the telephone number listed below. If the Examiner notes any further matters which the Examiner believes

may be expedited by a telephone interview, the Examiner is requested to contact the undersigned.

Respectfully submitted,

R. Scoop, et al.

A handwritten signature in black ink, appearing to read "Lisa V. Mueller", written over a horizontal line.

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